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February 20, 2003

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

To Whom It May Concern:

I am writing to you in an effort to convey my sentiments regarding a particular recent change in FDA policy which directly creates an anti-competitive situation for small, start-up businesses.

Let me first provide you with a little background before I explain my concern. We are a small privately funded medical device company. The product we market is an alternative to laser surgery and was acquired by us after the original company that developed the technology filed for bankruptcy. The product received FDA approval in 1999 after a very substantial, costly clinical trial. Unfortunately for us, the laser market has been quite successful and due to a number of factors our product has minimal acceptance at this time. However, we have completed additional clinical trials which could enhance our product's appeal and we are evaluating even further clinical trials for a therapeutic application of the product that has great promise.

With that as background, in 2002 a decision was made by the FDA, with Congressional approval, which required medical device manufacturers to pay, for the first time, a fee with pre-market applications. The purpose was to provide additional funding which could be used to expand resources at the FDA and, therefore, improve application processing times. This is an admirable goal, and for the big players in our industry, the costs are insignificant. For the smaller guys, struggling through an economic recession, chasing scarce investment dollars and running up sizable bills to run clinical trials, this can be a considerable disadvantage. This new policy, which does give monetary concessions to companies with lesser financial means, still makes the cost of an application difficult for a company of our size to afford. Please understand, that even with the reduced fees, this can mean one to two less people on our payroll.

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In an era of the big getting bigger, I find that this policy exacerbates a troubling situation. Some of the more significant breakthroughs in our industry, and many others, were created because someone had an idea and took a risk. For small and start-up companies, managing cash can be an everyday event. A hefty fee on top of the cost of development and a clinical trial just makes the challenge that much greater and without a doubt benefits the bigger, financially stronger companies. Instead of creating a more effective and economically favorable environment for small companies, we have let the lobbying of the industry leaders create a situation in which they benefit most -- faster processing of applications and another financial hurdle for the smaller guy. I do not disagree with the establishment of fees necessarily, if it truly produces a faster approval process, but I do not believe the graduated fee structure has been calibrated fairly for smaller companies. The $30 million breakpoint in sales between a full fee and a reduced fee is still too high and there need to be lower fees at the $1.0 million, $5.0 million and $10.0 million levels to balance the scales. In fact, I would go as far as to say the amount being borne by the bigger companies is too low.

A $1.0 billion dollar company would pay $154,000 to the FDA for a pre-market application and a $5.0 million company would pay $59,000. In terms of percentages, the $5.0 million company is paying 118 times more than the $1.0 billion company relative to their sales. At a smaller company, the $58,000 could very well fund two R&D technicians, where the $154,000 is the cost a of sales meeting at a larger company.

I would respectfully ask that you look into this situation on behalf of Addition Technology and other smaller companies like ours.

Thank you very much for your time and would appreciate your efforts in seeing what corrective steps can be taken. Similar letters have been sent to Mr. T. Thompson, Dr. Mark McClellan and other members of government.

Sincerely,

William M. Flynn
President & CEO